

1.2. Since the restriction has been traversed, the requirement that the unelected claims be cancelled should be held in abeyance.

2. Definiteness Issues

Claim 14: "for" (line 4) has been corrected to "from".

Claim 28: "such as" clause has been eliminated.

Claim 32: cancelled.

Claim 23: The "derivative" must now be derivable from the recited compound by not more than two reaction steps. Compare claim 33, presented October 12, 2001.

Claim 30: now dependent on composition claim 14.

Claims 23, 24: claim 24 is cancelled; claim 23 no longer dependent on cancelled 22.

Claim 31: no longer dependent on cancelled 15.

Also, with regard to the meaning of "orthophosphate", an inorganic compound was intended. We would consent to an examiner's amendment to insert --inorganic-- if this is considered necessary.

3. Prior Art Issues

Claim 14 has been amended to incorporate the limitation of claim 24, namely, encapsulation by a calcium free membrane materia, which at the body temperature of the lactating animal is solid at a pH value about 4.0 but which dissolves at pH below 4.0".

3.1. Anticipation by Ashmead

Claims 14, 16-18, 23-25, 28, 29 and 32-34, were rejected as anticipated by Ashmead. Ashmead discusses encapsulation at col. 3, line 59 ("Therefore, dosing in the form of capsules or tablets might be accomplished...."). No further particulars are given as to the nature of the "capsules or tablets", and hence it

cannot be said that Ashmead contemplates a "calcium-free membrane", per amended 14.

3.2. Anticipation by Laurent

Claims 14, 16-19, 25, 28, and 31-34, but not 24, were rejected as anticipated by Laurent. Since the rejection was not applied to 24, and claim 14 now incorporates the limitation of 24, the Examiner should concede that amended 14 avoids anticipation by Laurent.

3.3. Anticipation by "Polka" (Polak)

Claims 14, 16-19, 23-25, 28, 29 and 31-34 were rejected as anticipated by "Polka" (Polak). Polak says that his compositions may be orally administered in the form of "capsules". He has a more specific discussion of "microcapsules", which are said to have a "substantially water-insoluble wall" which is semipermeable. The chemical nature of the capsules and microcapsules is not addressed, so they cannot be said to be "calcium-free".

The Examiner also refers to "film forming" agents as "calcium free membranes". We believe this misconstrues Polak's disclosure. Polak teaches that "mucoadhesives" can be useful "for forming a gastro intestinal film". He does not teach that this mucoadhesive is used to encapsulate the active agent.

Polak also teaches that the mucoadhesives can be used to form a film on skin, to act as a topical barrier. Again, this is not encapsulation.

Moreover, while Polak lists various mucoadhesives, he does not teach providing them in calcium-free form, or teach that the film is formulated to dissolve at pH below 4. (The effectiveness of Polak's active ingredient at pH 3.5 is not relevant to our claim limitation.)

3.4. Obviousness over Shinkyo or Schaumann and SATO

Claims 14, 16-19, 23-25, 28, 29, 31-34 are rejected as obvious over Shinkyo, JP 63056258 or Schaumann DE 1255466 and SATO et al 5906842.

Shinkyo (JP 63056258) and Schaumann (DE 1255466) do not recite encapsulated forms of the compounds.

Sato (US 5,906,842) does not disclose encapsulation by a calcium-free membrane material, which at the body temperature of the lactating animal is solid at a pH value above 4.0 but which dissolves at pH below 4.0. Should the examiner hold, that Sato does disclose such a membrane material, the applicant finds that there is nothing in the prior art to suggest or motivate the combination of Sato with Shinkyo or Schaumann.

Rumen bypass is highly relevant for amino acids, which may be broken down under the conditions prevailing in the rumen (Sato column 1, lines 35-41). Such a problem is not expected by the administration of the compounds of the present invention. There is thus no a priori motivation for an encapsulation in a calcium free membrane material, which at the body temperature of the lactating animal is solid at a pH value above 4.0 but which dissolves at pH below 4.0.

The advantage of using an encapsulation in a calcium free membrane material, which at the body temperature of the lactating animal is solid at a pH value above 4.0 but which dissolves at pH below 4.0, is that the active compound(s) is(are) liberated only after passage of the ruminant forestomachs in the intestinal tract, where calcium uptake is reduced by the compounds according to the invention. By avoiding release of the compounds in the rumen, it is obtained that the compounds do not interfere with digestive processes taking place there.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The

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attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By: 
Peter P. Cooper
Reg. No. 28,005

624 Ninth Street, N.W.
Washington, D.C. 20001
Telephone: (202) 628-5197
Facsimile: (202) 737-3528
IPC:lms
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 24 and 32 have been cancelled.

Claims 14, 23, 28, 30 and 31 have been amended as follows:

14 (amended). A composition for preventing parturient hypocalcemia in an animal, comprising, in a suitable form for peroral administration, at least one compound which reduces the absorption of calcium [for] from the drinking water and/or from the ration of said animal, wherein the compound is [in] encapsulated [form] by a calcium-free membrane material, which at the body temperature of the lactating animal is solid at a pH value above 4.0 but which dissolves at pH below 4.0.

23 (twice amended). The composition according to claim 14 [or 22] where the compound is encapsulated by a compound selected from the group consisting of a fat, a soap, a stearate, a protein, a polysaccharide, a cellulose, a gum, a glycol, gelatine and a derivative derivable from [of] any such compound by not more than two reaction steps.

28 (amended). The composition according to claim 14 where the composition comprises at least one further ingredient [such as a vitamin, a mineral or a carrier].

30 (amended). The composition according to claim [1] 14, comprising two different compounds which reduce the absorption of calcium from the drinking water and/or from the ration of said animal.

31 (amended). The composition according to claim [15] 30, wherein one compound is a zeolite and the other compound is selected from the group consisting of oxalic acid, sodium oxalate, phytic acid, a phytate, a clay mineral, ethylenediaminetetraacetic acid (EDTA) and its sodium salts Na₂EDTA and Na₄EDTA, trisodium nitrilotriacetate monohydrate, trisodium nitriloacetate, pentasodium

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diethylenetriaminepentaacetate, trisodium N-hydroxyethyl-
ethylenediaminetriacetate, citric acid, a citrate, a
polyphosphate, a tripolyphosphate, an orthophosphate and a
cellulose phosphate.